



ADVANCED  
MEDICAL DEVICES  
INCORPORATED

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Premarket Notification  
Advanced Medical Devices, Inc.  
AMD Home Health Monitoring System

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: President

Date Prepared: December 18, 1995

Proprietary Name: AMD Home Health Monitoring System

Common/Usual Name: Self-Monitoring Blood Glucose Device

Classification Name: Test system, glucose (procode 75CGA)

**Device Description/Intended Use:** The AMD Home Health Monitoring System consists of the home-use, blood glucose meter, the AMD Home Health Glucose Monitor, with accessories, and the companion physician's monitoring device, the AMD PC Monitoring Station. The AMD Home Health Glucose Monitor contains the glucose measurement technology of the MediSense Pen 2 device. MediSense Companion 2 Test Strips and Control Solutions are to be used with the AMD Home Health Glucose Monitor.

The AMD Home Health Glucose Monitor testing system has been developed to allow rapid measurement of blood glucose (D-glucose) by using an electrochemical detection technique. This biosensor system employs a disposable dry reagent strip technology, based on the glucose oxidase method<sup>1</sup> for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (*Aspergillus niger*). When a blood drop is applied to the target area of the test strip, the glucose oxidase catalyzes the oxidation of glucose in the drop to produce gluconic acid. During the reaction, electrons are transferred by way of an electrochemical mediator to the electrode surface. This in turn generates a current that is measured by the Home Health Glucose Monitor. The size of the current generated is proportional to the amount of glucose present in the blood drop, thus giving an accurate reading of the blood glucose concentration.

<sup>1</sup> Cass, A.E.G. et al., Anal. Chem. 56 (1984) p.667.

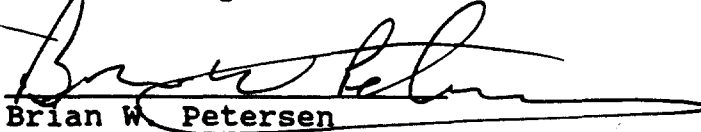
<sup>2</sup> Marks, V. & Dawson, A., B. Med. J. 1 (1965) p.293.

The computer-controlled Home Health Glucose Monitor facilitates efficient blood glucose testing and has an internal modem for the transmission of glucose test results to the remote AMD PC Monitoring Station. The AMD PC Monitoring Station is a personal computer-based system used in the clinical setting (e.g., physician's office, nurse's station, etc.) to receive and process blood glucose test data transmitted by the Home Health Glucose Monitor. This device allows remote clinical review of test results obtained in the patient's home.

**Predicate Devices:** The AMD Home Health Monitoring System is substantially equivalent to the MediSense Pen 2 Blood Glucose Monitoring System, the Lifescan, Inc. ONE TOUCH® II Blood Glucose Monitoring System, and the BioStore Technologies BioStore™ L Diabetes Data Management System (intended for use with ONE TOUCH® II System).

**Predicate Comparison:** A chart comparing the AMD Home Health Monitoring System to the cited predicate devices, demonstrating substantial equivalence, is attached.

**Submitted by:**



Brian W. Petersen  
President  
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DEVICE COMPARISON CHART

Device Characteristic	AMD Home Health Monitoring System	MediSense Pen 2 Blood Glucose Testing System	Lifescan ONE TOUCH II Blood Glucose Monitoring System	*BioStore Technologies *BioStore L Data Management System
Brief Device Description	1.Portable home-use blood glucose test meter with test strips and control solutions  2.Dedicated clinical-use computer system for receipt and management of patient blood glucose test results by clinician	Portable home-use blood glucose test meter with test strips and control solutions	1.Portable home-use blood glucose test meter with test strips and control solutions	* * * * *2. Dedicated home-use computer software for use by Lifescan ONE TOUCH II device patients for management of personal blood glucose test results and transmission of test data to remote clinical computer
Indication For Use	In vitro diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood	In vitro diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood	In vitro diagnostic use in monitoring whole blood glucose in patients diagnosed with diabetes mellitus by conventional means	* * * * *
Is Meter Hand-Held/Portable?	Yes	Yes	Yes	*N/A * *
Dimensions Length (in.): Width (in.): Height (in.):	6.00 3.50 1.25	3.65 2.15 .038	4.75 2.38 1.06	*N/A * * *

DEVICE COMPARISON CHART (cont.)

Device Characteristic	AMD Home Health Monitoring System	MediSense Pen 2 Blood Glucose Testing System	Lifescan ONE TOUCH II Blood Glucose Monitoring System	*BioStore Technologies *BioStore L Data Management System
Number of Control Buttons	4	1	1	*N/A * *
Display Type	Alphanumeric, 2-line, 24-character liquid crystal display (LCD)	Alphanumeric, 3-character LCD	Alphanumeric, 6-character LCD	*N/A * *
Power Source	Internal, rechargeable batteries with external DC power supply	Internal, non-replaceable battery	Internal, replaceable battery	*N/A * *
Estimated Battery Life	20 hours with fully-charged batteries	4000 glucose tests	1 year (@ 2 tests/day)	*N/A *
Assay Range	20-600 mg/dL (1.1-33.3 mmol/L)	20-600 mg/dL (1.1-33.3 mmol/L)	0-600 mg/dL (0-33.3 mmol/L)	*N/A *
Sample Volume	10-50 microliters	10-50 microliters	Not specified	*N/A *
Operating Temp. Range	64-86° F (18-30° C)	64-86° F (18-30° C)	59-95° F (15-35° C)	*N/A *
Operating Humidity Range	20-80% RH	20-80% RH	0-90% RH	*N/A *

**DEVICE COMPARISON CHART (cont.)**

<b>Device Characteristic</b>	<b>AMD Home Health Monitoring System</b>	<b>MediSense Pen 2 Blood Glucose Testing System</b>	<b>Lifescan ONE TOUCH II Blood Glucose Monitoring System</b>	<b>*BioStore Technologies *BioStore L Data Management System</b>
<b>Test Strips Specified</b>	<b>MediSense Companion 2 Blood Glucose test Strips (private-labeled for AMD)</b>	<b>MediSense Companion 2 Blood Glucose test Strips</b>	<b>Lifescan ONE TOUCH Test Strips</b>	<b>*N/A * *</b>
<b>Control Solutions Specified</b>	<b>MediSense Companion 2 HIGH and LOW Control Solutions (private-labeled for AMD)</b>	<b>MediSense Companion 2 HIGH and LOW Control Solutions (private-labeled for AMD)</b>	<b>Lifescan ONE TOUCH Normal Glucose Control Solution-Blue Formula</b>	<b>*N/A * *</b>